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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------------|
| 10/531,547 | 11/16/2005 | Chaitan Khosla | STAN-258US5 | 3888 |
| 77974 | 7590 | 12/11/2008 | | |
| Stanford University Office of Technology Licensing Bozicevic, Field & Francis LLP 1900 University Avenue Suite 200 East Palo Alto, CA 94303 | | | EXAMINER CHEU, CHANGHWA J | |
| | | | ART UNIT 1641 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/531,547 | Applicant(s) KHOSLA ET AL. | |
| | Examiner JACOB CHEU | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 1-22 and 25-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23,24 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>6/30/06; 7/14/06; 2/26/08; 4/18/08</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION***Election/Restrictions***

1. Applicant's election of Group V, claims 23-24 and 29, directed to an antibody, in the reply filed on 9/25/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-22, 25-28 are withdrawn from further consideration.
3. Currently, claims 23-24 and 29 are under examination.

Specification

It is noted Section 0057 [Determination of whether an oligopeptide is immunogenic for a particular patient is "radily" determined by standard T cell activation assay known to those of skill in the art"] (See Publication 20060240475) The misspelling "radily" should be "rapidly". Similarly, Section 0088, in the middle part, [such as, in particular, the 33-mer oligopeptide of the invention, dramatically increases their affinity for HLA-DQ2, the class II MHC allele present in > 90% Celiac Sprue patients; and presentation of these "*deamidat d*" epitopes by DQ2 positive antigen presenting cells effective...]. The misspelling "deamidat d" should be "deamidated". Correction is needed.

Claim Objections

4. Claims 23-24 are objected to because of the following informalities: It is noted that claims 23-24 direct to an antibody cell line or antibody. However, these claims lack the features as to how one produce such cell line or antibody. It is suggested Applicant incorporates the essential features from claims 1 and 12 into the claim language. Appropriate correction is required.

Note, the language in claim 1 cannot be a valid peptide when $n=0$ and $y=0$. In addition, the language in claim 12 "conservatively modified variant thereof" may need support from disclosure to satisfy 35 USC 112, first paragraph, with respect to "written description" and "enablement". Thus far, no particular portion of the peptide is discussed. Also, such feature needs a functionality correlated with the peptide in support of enablement/written description.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 23-24 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (WO 03104273) in view of Lewicki et al. (US 4656253).

Anderson et al. teach a method of diagnosing celiac Sprue disease. Anderson et al. teach detecting polypeptide refractory to digestion which then causes such disease. The polypeptides include PQPQLPYPQ (A2), or PYPQPQLYP (A3) (See page 71, Example 14). Although Anderson et al. do not explicitly teach producing antibody (using hybridom cell line) against these polypeptide, it would have been obvious to one ordinary skill in the art to make antibodies once the antigen has been isolated as taught by Lewicki et al. (Col. 3, line 62-68). Furthermore, *Board of Patent Appeals and interferences* has taken the position that once an antigen has been isolated and sequenced, the manufacture of monoclonal antibodies against it is *prima facie* obvious. See *Ex parte Ehrlich*, 3 USPQ

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2d 1011 (PTO Bd. Pat. APP. & Int. 1987), Ex parte Sugimoto, 14 USPQ 2d 1312 (PTO Bd. Pat. APP. & Int. 1990). It is also noted that SEQ ID No. 12 encompasses the above mentioned peptide because Anderson et al. consider these peptides as epitopes.

Therefore, if the antibodies can detect PQPQLPYPQ (A2), or PYPQPQLYP (A3), then the antibodies can also specifically bind to SEQ ID NO. 12.

8. Claims 23-24 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arentz-Hansen et al. (J. Exp. Med. 2000 Vol. 191, page 603-612; Applicant submitted IDS information) in view of Lewicki et al..

Arentz-Hansen et al. study Celiac Sprue disease. Arentz-Hansen et al. study several alpha-gliadins for the CD412/CD387 recognition. Arentz-Hansen et al. found out one particular peptide, alpha 2 (62-75) PQPQLPYPQPQLPY, has particular function to stimulate T cell recognition (See Table II; page 606). Such 14-mer peptide is encompassed within SEQ ID NO. 12. Similarly, as discussed above, it would have been obvious to produce antibody when the antigen is identified and characterized.

Conclusion

9. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACOB CHEU whose telephone number is (571)272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacob Cheu/
Examiner, Art Unit 1641